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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/375,169	08/16/1999	CAROLYN R. AITA	26767-1000	4691

7590 06/10/2003

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[REDACTED] EXAMINER

MCNEIL, JENNIFER C

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1775

DATE MAILED: 06/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



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23422            7590            03/12/2003

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[REDACTED] EXAMINER

MCNEIL, JENNIFER C

ART UNIT	PAPER NUMBER
1775	20

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/375,169	AITA ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Jennifer McNeil	1775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 December 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3,4,7-10,12-16,18,19,21-28,30,31 and 33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 21-26 is/are allowed.
- 6) Claim(s) 1,3,4,7,8,12-16,18,19,27,28,30,31,33 is/are rejected.
- 7) Claim(s) 9 and 10 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)  
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.                    6) Other:

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4, 7-10, 12-16, 18, 19, 28, 30, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites an inner coating having at least one bilayer formed of different ceramic materials. Does this mean the bilayer is formed of a first layer of a first ceramic material and a second layer of a second ceramic material different from the first ceramic material? Please clarify.

Claim 18 recites a "second layer", however, a first layer is never established.

Claim 28 recites a "second layer", however, a first layer is never established.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4, 7, 8, 12-16, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aita et al (US 5,472,795). Aita et al teach a multilayer nanolaminate containing polycrystalline zirconia. The substrate or support (11) may be of any desired material including glass or plastic. Thin layers of zirconia are alternated with layers of a hard ceramic material. Two or more layers are preferably alternately coated onto the support. A multiplicity of these layers would serve as bilayers. The hard ceramic may be made of materials such as oxides, nitrides, and carbide (col. 2, lines 61-67; col. 3, lines 1-24), and these ceramic layers have a thickness in the range of 3 nm to about 1 micron (col. 5, lines 35-51). Aita et al do not give specific examples of additional hard ceramics other than a list including alumina, silicon carbide, boron nitride, or titanium nitride. Absent a showing of unexpected

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results, it is the examiner's position it would have been obvious to one of ordinary skill in the art at the time of the invention to use any biocompatible, hard ceramic material known to one of skill in the art as a coating in Aita.

Regarding claim 4, the same of the prior art is considered to possess the same characteristics.

Regarding claim 7, the inner coating of zirconia may be less than 6nm thick (col. 4, lines 56-67).

Regarding claim 12, 6 nm is considered to meet the limitation "up to about 1 micron".

Regarding claim 14, the multiplicity of layers is considered a bilayer, and the materials comprising the layers are commensurate with those taught by applicant and are considered to possess the same characteristics of hardness and toughness.

Regarding claim 15, the alternating layers are 3 nm to 1 micron.

Regarding claim 27, Aita teaches a substrate (11) that may be plastic (polymer) and a plurality of layers that may be of nanoscale (3nm to 1 micron) thickness, and may be comprised of alumina and zirconia or other ceramics listed in col. 3, lines 1-6.

Claims 18, 19, 28, 30, 31, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aita et al (US 5,472,795) in view of Davidson (US 5,782,910). Aita et al teach a multilayer nanolaminates containing polycrystalline zirconia. The substrate or support (11) may be of any desired material including glass or plastic. Thin layers of zirconia are alternated with layers of a hard ceramic material. Two or more layers are preferably alternately coated onto the support. A multiplicity of these layers would serve as bilayers. The hard ceramic may be made of materials such as oxides, nitrides, and carbide (col. 2, lines 61-67; col. 3, lines 1-24), and these ceramic layers have a thickness in the range of 3 nm to about 1 micron (col. 5, lines 35-51). Aita et al do not give specific examples of additional hard ceramics other than alumina, silicon carbide, boron nitride, or titanium nitride. Davidson '910 teaches an implant having coatings of hard ceramics. These hard ceramics include titanium nitride, titanium oxide, zirconium oxide, zirconium nitride, and zirconium or titanium carbide (col. 6, lines 38-54). As it is taught by Davidson that hard ceramic coatings such as titanium nitride and zirconium nitride are

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equivalents, it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the hard ceramic ZrN for the hard ceramic TiN in the invention of Aita et al.

Regarding claim 7, the inner coating of zirconia may be less than 6nm thick (col. 4, lines 56-67).

Regarding claim 4, the same of the prior art is considered to possess the same characteristics.

Regarding claim 12, 6 nm is considered to meet the limitation "up to about 1 micron".

Regarding claims 19 and 30, it would have been obvious to one of ordinary skill in the art at the time to use any material known in the art that is hard and biocompatible.

#### *Allowable Subject Matter*

Claims 9, and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 21-26 are allowed.

#### *Response to Arguments*

Applicant has amended independent claim 1 to reflect a bilayer with an aluminum nitride layer thereon. This combination was addressed in the previous office action with the argument that any biocompatible, hard ceramic known in the art would be obvious to use as the hard ceramic layer. Applicant has not offered any argument against this combination and has not offered any evidence that aluminum nitride would not be considered a biocompatible, hard ceramic. This rejection of claim 1 and its dependent claims has been maintained.

Applicant has amended independent claim 18 to reflect a bilayer formed of different materials. As stated in Aita, the layers are formed of alternating (different) compositions, and it is the position of the examiner that the outer layer of this plurality of alternating layers is considered the outer coating. The same applies to claim 28.

Upon closer consideration, claims 14, 15, and 27 have been rejected over Aita for the reasons stated above.

Applicant's amendments have overcome the rejections of Davidson '951 in view of Davidas '305 and Davidson '910.

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Applicant argues that the claims are directed to a coating or device with a coating having a bilayered inner coating and outer coating of aluminum nitride. This argument is commensurate with only claim 1 and its dependent claims. Claims 18, 28 include zirconium nitride as an alternate ceramic coating. As stated above, applicant has not offered any argument against the obvious rejections, and the rejection is held. It is the examiner's position that the claims do not reflect a bilayer of at least a first ceramic material and a second ceramic material, and an outer coating of a ceramic material different from the materials in the bilayer. It appears that this is what applicant is intending to claim, however, the outer coating, as currently claimed, and is considered the final coating of the alternating layers of Aita.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer McNeil whose telephone number is 703-305-0553. The examiner can normally be reached on Monday through Friday, 9:30AM-6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones can be reached on 703-308-3822. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer McNeil  
Examiner  
Art Unit 1775

  
JCM  
March 10, 2003